

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

THOMAS YOUNG,

Plaintiff,

v.

JOHNSON & JOHNSON,

Defendant.

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Civil Action No. 11-4580 (JAP)

OPINION

This matter comes before the Court on Defendant Johnson & Johnson’s motion to dismiss Plaintiff Thomas Young’s complaint pursuant Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). Plaintiff opposes the motion. For the reasons set forth below, Defendant’s motion to dismiss will be granted.

I. BACKGROUND

This proposed class action is comprised of a variety of allegations relating to the labeling, marketing, and advertising of Benecol Regular Spread and Benecol Light Spread (collectively, “Benecol”), butter/margarine substitutes manufactured by Defendant.¹ Plaintiff alleges that Defendant misrepresented the nutritional content and health benefits of Benecol and, as a result, was “able to command a premium price by deceiving consumers about the healthfulness of its product and distinguishing itself from similar spread and margarine products.” Compl. ¶ 2.

As the basis for his allegations, Plaintiff identifies a number of specific claims made on the packaging and in the marketing of Benecol that he alleges are “false and misleading.” Compl. ¶¶ 3-5. Specifically, he points to claims that Benecol is: “Proven to Reduce Cholesterol”; contains “NO TRANS FAT, directly above a symbol of a heart to convey heart

¹ Benecol and Benecol Light are products of McNeil Nutritionals, LLC, a wholly-owned subsidiary of Defendant.

health”; contains “No Trans Fatty Acids”; contains “1/2 the fat and calories of margarine”; is an “Excellent Source of Vitamin E”; is “Part of a Healthy Lifestyle”; is a “heart healthy alternative to butter”; and that plant stanol esters, an ingredient in Benecol, has certain health benefits.

Compl. ¶¶ 3-4, 14-15. Plaintiff alleges that all of these claims are misleading because Benecol “contains a highly unhealthy, non-nutritious ingredient known as partially hydrogenated oil,” which contains trans fats. Compl. ¶¶ 4-5, 16-17.

In a Five-Count Complaint filed with this Court on August 6, 2011, Plaintiff asserts that Defendant’s conduct gives rise to claims for: (1) violation of the New Jersey Consumer Fraud Act; (2) violation of the New York General Business Law; (3) breach of express warranties; (4) breach of the implied warranty of merchantability; and (5) unjust enrichment. On October 18, 2011, Defendant filed the instant motion to dismiss.

II. STANDARDS OF REVIEW

Federal Rule of Civil Procedure 12(b)(1) allows a party to move for dismissal of claims based on a lack of subject matter jurisdiction. Challenges to jurisdiction under 12(b)(1) may be either facial or factual. *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n.3 (3d Cir. 2006). A facial attack challenges the sufficiency of the pleadings, and the trial court “must consider the allegations of the complaint as true.” *Id.* However, in a factual attack, plaintiff’s allegations are afforded no presumption of truthfulness, *id.*, and the trial court may review evidence outside the pleadings. *Gould Electronics Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000). The plaintiff bears the burden of establishing that jurisdiction exists. *Petruska*, 462 F.3d at 302 n.3.

Under Federal Rule of Civil Procedure 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a claim upon which relief can be granted. The Supreme Court set forth the standard for addressing a motion to dismiss under Rule 12(b)(6) in *Bell Atl. Corp. v.*

Twombly, 550 U.S. 544 (2007). The *Twombly* Court stated that, “[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff’s obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 555 (internal citations omitted). Therefore, for a complaint to withstand a motion to dismiss under Rule 12(b)(6), the “[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* (internal citations and footnote omitted).

More recently, the Supreme Court emphasized that, when assessing the sufficiency of a civil complaint, a court must distinguish factual contentions and “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). A complaint will be dismissed unless it “contain[s] sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Id.* (quoting *Twombly*, 550 U.S. at 570). This “plausibility” determination will be “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Id.* at 1950. To help guide a district court’s evaluation of a motion to dismiss, the Third Circuit has established a three-part analysis:

First, the court must “tak[e] note of the elements a plaintiff must plead to state a claim.” Second, the court should identify allegations that, “because they are no more than conclusions, are not entitled to the assumption of truth.” Finally, “where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.”

Santiago v. Warminster Twp., 629 F.3d 121, 130 (3d Cir. 2010) (quoting *Iqbal*, 129 S.Ct. at 1947-50)).

III. DISCUSSION

A. Standing

Defendant first argues that Plaintiff lacks standing to pursue his claims. Standing is a threshold jurisdictional requirement derived from Article III's case-or-controversy requirement. U.S. Const. art. III, § 2, cl. 1. To satisfy "the irreducible constitutional minimum of standing," the plaintiff bears the burden of establishing three elements:

First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly ... trace[able] to the challenged action of the defendant, and not ... the result [of] the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992). Although all three elements must be met, "the injury-in-fact element is often determinative." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 (3d Cir. 2009).

Here, Plaintiff has not sufficiently pled an injury-in-fact. The essence of the allegations set forth in his complaint relate to the presence of a small amount of partially hydrogenated oils in Benecol. Plaintiff alleges that, because Benecol contains partially hydrogenated oils—which, in his view are "dangerous, unhealthy and non-nutritional" in any amount, Compl.¶ 20 — Defendant's various claims as to the health benefits and composition of the spread are false and misleading. Nevertheless, although he cites various studies and sets forth allegations concerning the health dangers of consuming partially hydrogenated oils, Plaintiff does not allege that he himself suffered any adverse health consequences. Indeed, he does not even allege that he ever actually consumed Benecol, and instead merely avers that he "purchased Defendant's Products fairly regularly during a five-year period, at least one every couple of months." Compl. ¶ 9. For

purposes of the standing inquiry, however, apprehension about a possible future injury is insufficient to establish injury-in-fact. *See, e.g., Lujan*, 504 U.S. at 560-61 (an injury-in-fact must be “(a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical”).

Moreover, Plaintiff’s allegations that Defendant’s various health claims are misleading are belied by both Food and Drug Administration (“FDA”) regulations regarding trans fats as well as disclosures made on Benecol’s packaging. As set forth in more detail below, the FDA requires that trans fat levels less than 0.5 grams per serving “shall be expressed as zero.” 21 C.F.R. § 101.9(c)(2)(ii). Correspondingly, an “insignificant amount” of a listed nutrient such as trans fat is “defined as that amount that allows a declaration of zero on nutrition labeling.” 21 C.F.R. § 101.9(f)(1). Accordingly, because Benecol contains less than 0.5 grams of trans fat per serving, Defendant’s claims that Benecol contains “NO TRANS FAT” and “No Trans Fatty Acids” are consistent with FDA regulations.² *See, e.g., Koronthaly v. L’Oreal USA, Inc.*, 374 F. App’x 257, 259 (3d Cir. 2010) (concluding that “Koronthaly’s argument that she was misled into purchasing unsafe lipstick products is belied by the FDA’s report finding that the lead levels in the Defendants’ lipsticks were not dangerous and therefore did not require warnings”).

Additionally, as Plaintiff acknowledges in his complaint, Benecol’s packaging discloses that it contains a small amount of partially hydrogenated oils and trans fats. *See* Compl. ¶ 18. Specifically, it contains a disclaimer that states: “A small amount of partially hydrogenated oils are used in Benecol Spreads . . . As a result, Benecol Spreads, contain an extremely low level of

² Similarly, as discussed below, Defendant’s various other health-related claims, including those relating to the health benefits of plant stanol esters and the cholesterol-reduced effects of Benecol, are consistent with current FDA regulations. *See infra* III(B); FDA Letter, Feb. 14, 2003; Proposed Final Rule, 75 Reg. 76526 (Dec. 8, 2010); 65 Fed. Reg. 54686, 54713-54717; 21 C.F.R. §§ 101.83(b)(2), 101.14(a)(1), 101.13(j), § 101.54(b)(1). Furthermore, Plaintiff does not dispute the accuracy of most of those claims, and, in event, his allegations regarding those claims do not establish injury-in-fact or alter the Court’s standing analysis, as they are premised on the same assertion that the presence of any partially hydrogenated oils and trans fats renders Benecol unhealthy and all health-related statements misleading.

trans fat. The FDA allows foods containing less than 0.5 grams of trans fat/serving to be labeled 0 grams trans fat, since this is considered an insignificant amount.” Greenbaum Cert., Ex. B.³ Moreover, the ingredient list indicates that Benecol contains partially hydrogenated oil. *Id.* Therefore, the presence of small amounts of partially hydrogenated oils and trans fats in Benecol—the foundation of Plaintiff’s complaint and the basis for his argument that Defendant’s health claims are false and misleading—was fully disclosed to him during the five-year period that he allegedly purchased Benecol.

Finally, Plaintiff’s contention that he satisfies the injury-in-fact requirement because he alleges that he was deprived of the “benefit of the bargain,” received a product of inferior quality, and paid a premium price for Benecol because he believed “that it was healthy, when in fact it was not because it contained dangerous partially hydrogenated oils” is unavailing. Compl. ¶¶ 9, 38, 44, 50, 55. His purchases of Benecol were not made pursuant to a contract and, beyond relying on his own subjective belief as to the unhealthy nature of even small amounts of trans fats, he does not set forth allegations as to how he paid a premium for Benecol or received a product that did not deliver the advertised benefits. *See Koronthaly*, 374 F. App’x at 259 (rejecting plaintiff’s argument that injury-in-fact was loss of “benefit of the bargain,” as her purchases were not made pursuant to a contract); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319-21 (5th Cir. 2002)(rejecting “benefit of the bargain” argument and dismissing for lack of standing); *Medley v. Johnson & Johnson*, 2011 WL 159674, at *2 (D.N.J. Jan. 18, 2011)(finding that plaintiffs lacked standing where the economic injury for which they sought redress was the

³ Because Plaintiff relied on and quoted from Benecol’s packaging, the Court may consider this document in addressing Defendant’s motion to dismiss. *See Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993)(it is appropriate to consider “undisputedly authentic document[s] that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff’s claims are based on the [attached] document[s]”); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

price they paid for shampoo and no adverse health consequences were pled).⁴ Indeed, as established above, Plaintiff's complaint amounts to no more than subjective allegations that the presence of any amount of trans fat and partially hydrogenated oils renders Defendant's health claims misleading and Benecol unhealthy. Such allegations, however, are insufficient to establish injury-in-fact, particularly in light of Plaintiff's failure to allege any adverse health consequences, the consistency of Defendant's claims with relevant FDA regulations, and the disclosures made on Benecol's packaging indicating the presence of small amounts of partially hydrogenated oils and trans fats. *See, e.g., Lujan*, 504 U.S. at 560-61 (an injury-in-fact must be "(a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical"); *Koronthaly*, 374 F. App'x at 259 (finding that plaintiff's subjective allegations that trace amounts of lead in lipsticks is unacceptable to her do not constitute an injury-in-fact sufficient to confer Article III standing). Accordingly, Plaintiff lacks standing to pursue this action.

B. Preemption

Defendant also challenges Plaintiff's claims on the ground that they are preempted by the Federal Food, Drug and Cosmetic Act ("FDCA"), as amended by the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343-1. The doctrine of preemption is rooted in the Supremacy Clause of the United States Constitution. U.S. Const. art. IV, cl. 2. Under the Supremacy Clause, "federal law may be held to preempt state law where any of the three forms of preemption doctrine may be properly applied: express preemption, field preemption, and implied conflict preemption." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334-35 (3d Cir. 2009)(citing *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713

⁴ Plaintiff's reliance on *Zebersky v. Bed Bath & Beyond, Inc.*, 2006 WL 3454993 (D.N.J. Nov. 28, 2006) is misplaced. In that case, the plaintiffs alleged that the defendant made affirmative misrepresentations as to the thread counts in certain bed linen products, specifically by representing that the bed linens contained a thread count higher than that actually present. Here, however, no similar allegations are made, and Defendant disclosed the presence of partially hydrogenated oils and trans fats in Benecol. In essence, Plaintiff simply subjectively believes that the presence of any amount of trans fat renders Benecol unhealthy and its health-benefits' claims misleading.

(1985)). In areas of traditional state regulation, including the regulation of food and beverage labeling and branding, there is a presumption against preemption. *Id.* (internal citations omitted).

Relevant to the instant case, the NLEA contains express preemption provisions that provide, in pertinent part, that no state may impose any requirement respecting any nutritional labeling or nutrient content claims “that is not identical to the requirement” imposed by the Act. 21 U.S.C. §§ 343-1(a)(4) and (a)(5). Thus, a state statute or cause of action is preempted when it “would impose a requirement that is not the same as the federal requirement.” *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 93 (D.N.J. 2011) (internal citations omitted).

Here, Plaintiff’s claims are preempted by the NLEA. With regard to Defendant’s statements that Benecol contains “NO TRANS FAT” and “No Trans Fatty Acids,” as set forth above, FDA regulations require that trans fat levels less than 0.5 grams per serving “shall be expressed as zero.”⁵ 21 C.F.R. § 101.9(c)(2)(ii). Similarly, an “insignificant amount” of a listed nutrient such as trans fat is required to “be defined as that amount that allows a declaration of zero on nutrition labeling.” 21 C.F.R. § 101.9(f)(1).⁶ Thus, Plaintiff’s claims regarding Defendant’s statements—in essence, that they are false and misleading because any amount of trans fat is unhealthy and not “insignificant”—are expressly preempted because they seek to

⁵ “No” and “0” are synonymous. Additionally, Plaintiff’s assertion that Defendant’s claims that Benecol contains no trans fat are misleading because a reasonable consumer would mistakenly believe that the entire product contains less than 0.5 grams of trans fat defies logic. As noted in *Chacanaca*, “consumers can presumably infer that, while each [serving of Benecol] contains at most trivial amounts of trans fat, consumption of several [servings of Benecol] could entail non-trivial amounts (that is amounts that exceed 0.5 gram).” *Chacanaca*, 752 F. Supp. 2d at 1120. Moreover, as Defendant points out, the only relevant measure as determined by the FDA is amount per serving, the packaging identifies the presence of partially hydrogenated oils in numerous locations and includes a disclaimer, and, furthermore, no reasonable consumer would consume an entire tub of Benecol as one serving.

⁶ Plaintiff’s argument that these regulations apply only to Nutrition Box information, and that the claims made by Defendant are on different parts of the packaging and are therefore not preempted is without merit. FDA regulations provide that the same nutritional content claims authorized in the Nutrition Fact box can be repeated outside of that box and are subject to the same rules; thus, even though Defendant’s statements appear on other parts of Benecol’s packaging and label, Plaintiff’s claims are expressly preempted. *See* 21 C.F.R. § 101.13(i)(3); 58 Fed. Reg. 44020, 44024-25 (Aug. 18, 1993); *see also Carrea v. Dreyer’s Grand Ice Cream, Inc.*, No. 11-15263, 2012 WL 1131526, at *1 (9th Cir. April 5, 2012) (concluding that the “0g Trans Fat” statement on food packaging outside the Nutrition Facts box is still subject to the express preemption provision of the NLEA); *Chacanaca*, 752 F. Supp. 2d at 1118-22. Furthermore, as discussed above, Benecol’s packaging contains a disclaimer disclosing the presence of partially hydrogenated oils and trans fat.

impose requirements that are inconsistent with federal law. *See, e.g., Carrea v. Dreyer's Grand Ice Cream, Inc.*, No. 11-15263, 2012 WL 1131526, at *1 (9th Cir. April 5, 2012)(holding that closely analogous claims regarding “0g Trans Fat” statement on front of packaging are expressly preempted by the NLEA where the product contained less than 0.5 grams of trans fat per serving); *Chacanaca v. The Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1121 (N.D. Cal. 2010)(concluding that plaintiffs’ claims were preempted because “if ‘nutritionally insignificant amounts’ of less than 0.5 gram trans fats means the same thing, according to Agency regulations, as “0 grams,” then the use of the latter language in an express nutrient content claim would *not* be misleading within the meaning of section (r) or any of its regulations”).

Similarly, Plaintiff’s claims as to Defendant’s statements regarding plant stanol esters and the cholesterol-reducing benefits of consuming Benecol are preempted. As an initial matter, those claims, along with the balance of Plaintiff’s complaint, are premised on the same allegations and argument already addressed and rejected by the Court—specifically, that the presence of any amount of trans fat and partially hydrogenated oils in Benecol renders all of Defendant’s health and nutrient-content claims misleading.⁷ Furthermore, FDA regulations provide that “scientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels,” 21 C.F.R. § 101.83(b)(2); *see also* FDA Letter, Feb. 14, 2003; Proposed Final Rule, 75 Reg. 76526 (Dec. 8, 2010), and, correspondingly, that claims that are “based on, and consistent with, the conclusions” of § 101.83 are also authorized. 21 C.F.R. § 101.14(d)(2)(i). Therefore, because Plaintiff’s claims seek to impose

⁷ With regard to the other claims that Plaintiff specifically identifies in the complaint, Defendant’s use of a heart symbol is consistent with FDA regulations, *see* 21 C.F.R. § 101.14(a)(1), as are its statements that Benecol Light has “1/2 the fat and calories of margarine,” *see* § 101.13(j), and that Benecol is an “excellent source of Vitamin E,” *see* § 101.54(b)(1). Moreover, as noted above, Plaintiff does not affirmatively contest the truth of these statements, and instead relies on the same allegations already addressed—that all health-related claims are misleading because of the presence of trans fats and partially hydrogenated oils in Benecol.

requirements that differ from those imposed by the FDA's regulations, they are expressly preempted by the NLEA.⁸

IV. CONCLUSION

For the reasons set forth above, Defendant's motion to dismiss is granted. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: April 19, 2012

⁸ Although it need not reach Defendant's alternative arguments for dismissal, the Court notes that Defendant's argument that Plaintiff's complaint is subject to dismissal for failure to sufficiently plead the requisite elements of his claims appears to have merit.